Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

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DATE: April 30, 2009

TO: All Local Health Departments
Attn: Chief Food Specialist

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: Nature & Health Co.- Recall of Libimax, a Product Marketed as a Dietary Supplement

Suggested Action: **CLASS Unidentified; Recall of Libimax, a Product Marketed as a Dietary Supplement; Recommend notification to establishments that may carry this product via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled was distributed in neighboring States of Illinois and Ohio but was NOT distributed in the State of Indiana. The recalled Libimax is sold as a 1 capsule individual pack or 10-capsule and 20-capsule plastic bottles in retail stores in California, Georgia, Illinois, Texas, and Ohio. The product label neither states it contains tadalafil nor warns consumers with high blood pressure not to ingest the product. Detail information is not available at this time. Please notify this office at 317-233-7360 if any recalled product is found.

Nature & Health Co. Issues Voluntary Nationwide Recall of Libimax, a Product Marketed as a Dietary Supplement

Contact:
Boksik (Aka Robert) Kim
(714) 257-1800

FOR IMMEDIATE RELEASE -- Brea, CA – April 27, 2007 -- **Nature & Health Co**., located in Brea, California, announced today that it is conducting a voluntary nationwide recall of the company's supplement product sold under the name Libimax. The Company has been informed by representatives of the Food and Drug Administration (FDA) that lab analysis by FDA of Libimax samples found the product contains tadalafil, an active ingredient of an FDA-approved drug for erectile dysfunction (ED), making Libimax an unapproved drug. FDA advised that this poses a threat to consumers because tadalafil may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels. According to the FDA, consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. FDA advises that ED is a common problem in men with these conditions, and they may seek products to enhance sexual performance. FDA advises that tadalafil, may cause side effects, such as headaches and flushing.

The recalled Libimax is sold as a 1 capsule individual pack or 10-capsule and 20-capsule plastic bottles in retail stores in California, Georgia, Illinois, Texas, and Ohio. The product label neither states it contains tadalafil nor warns consumers with high blood pressure not to ingest the product.

Consumers who have Libimax in their possession should stop using it immediately and contact their physician if they experienced any problem that may be related to taking this product. The public is encouraged to submit a report of any serious adverse events that occur with the use of Libimax to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail [to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

Nature & Health Co. is committed to providing accurate information about its products because of concern for the health and safety of consumers. Nature & Health Co. is working with the FDA in the recall process. It sincerely regrets any inconvenience to customers.

No illnesses have been reported to the Company to date in connection with this product.

Consumers should return any unused Libimax, for a refund of the full purchase price or price for the unused portion, to the retail location where it was purchased or to contact Nature & Health directly at (714) 257-1800 Monday – Friday, 8am to 5pm or by email at sales@naturenhealth.com to receive further instructions for returning the product or with any questions.

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